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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,413	08/07/1998	HANS JOSEF STAUSS	RPMS102	9623

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	35

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/101,413	Applicant(s) Stauss, H.
	Examiner G.R. Ewoldt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 5/30/02 and 8/16/02 .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-3, 5-18, and 27 is/are pending in the application.

4a) Of the above, claim(s) 9-13 and 27 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-3, 5-8, and 14-18 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 34
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The request for a continued prosecution application (CPA) under 37 CFR 1.53(d) filed on [1] is acknowledged. 37 CFR 1.53(d)(1) was amended to provide that the prior application of a CPA must be: (1) a utility or plant application that was filed under 35 U.S.C. 111(a) before May 29, 2000, (2) a design application, or (3) the national stage of an international application that was filed under 35 U.S.C. 363 before May 29, 2000. See *Changes to Application Examination and Provisional Application Practice*, interim rule, 65 *Fed. Reg.* 14865, 14872 (Mar. 20, 2000), 1233 *Off. Gaz. Pat. Office* 47, 52 (Apr. 11, 2000). Since a CPA of this application is not permitted under 37 CFR 1.53(d)(1), the improper request for a CPA is being treated as a request for continued examination of this application under 37 CFR 1.114. *See id.* at 14866, 1233 *Off. Gaz. Pat. Office* at 48.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 5/30/02 and 8/16/02 have been entered.

3. A restriction was required under 35 U.S.C. § 121 in the parent application, as set forth in Paper No. 8, mailed 8/26/99.

Applicant elected Group II, claims 1-18, and the species, hematologic malignancies and GATA-1 and WT-1, with traverse. This restriction requirement is hereby reiterated.

The requirement is still deemed proper for the reasons of record as set forth in Paper No. 10, mailed 1/19/00, and is therefore made FINAL.

4. Claims 9-13 and 27 are withdrawn from further consideration by the examiner as being drawn to non-elected species of the elected invention.

Claims 1-3, 5-8, and 14-18 read on the elected species and are being acted upon.

5. New corrected drawings must be filed with the changes incorporated therein. See the PTO Form 948, mailed 1/19/00. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948. All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections. Note that the filing of corrected drawings may no longer be held in abeyance until such time as claims are found allowable. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

6. In view of Applicant's amendment and response, filed 5/30/02 and reiterated 8/16/02, the previous rejection under the first paragraph of 35 U.S.C. 112 for the recitation of:

A) "A method of killing cells in a patient" (Claim 1),

B) "and the CTLs kill the presenting cells" (Claim 1),

C) wherein "the cells to be killed" (Claims 1),

has been withdrawn.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3, 5-8, and 14-18 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record, as set forth in Papers No. 22 and 25, mailed 6/28/01 and 12/11/01, respectively.

Applicant's arguments, filed 5/30/02 and reiterated 8/16/02, have been fully considered but have not been found persuasive. Applicant does not provide specific arguments regarding this rejection but instead provides a single argument that the specification discloses sufficient examples of the claimed invention to render all claims patentable. It remains the Examiner's position, however, that neither the specification nor claims adequately delineate the metes and bounds of the claimed invention, particularly as said claims recite an "abnormal antigen" or a "mutant polypeptide".

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-3, 5-8, and 14-18 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record, as set forth in Papers No. 22 and 25, mailed 6/28/01 and 12/11/01, respectively.

Applicant's arguments, filed 5/30/02 and reiterated 8/16/02, have been fully considered but have not been found persuasive. Applicant argues that the written description requirement can be met by "showing that more than one species of antigen, indicative of the breadth of the genus, can be targeted using the CTLs to kill cells having the antigens on their surfaces," followed by assertions that the specification makes such a showing. It is the Examiner's position that said showing has not been made as

the specification discloses *no* "abnormal antigens" nor *any* "mutant polypeptides." Accordingly, it is unclear how the specification can be said to provide an adequate written description for the invention of the instant claims.

11. The following are New Grounds for Rejection.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 5-8, and 14-186 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Falkenburg et al. (1993) as evidenced by Wu et al. (1995, of record).

Falkenburg et al. teaches a method of killing leukemic cancer cells in a human patient comprising administering to the patient a therapeutically effective amount of CTL, or a clonal population thereof (which would be substantially free of other cell types), wherein the CTLs have a different HLA class I complex than the cells to be killed (see particularly Abstract and Discussion). Note that the specific recognition of a peptide on the cells to be killed is a well-known inherent property of CTL killing. Additionally, absent any specific definition in the specification, the antigen recognized by the CTLs of the reference can be considered to be an abnormal antigen, or a mutant polypeptide antigen, or an abnormally elevated antigen. Further note that it is well known that preceding any bone marrow transplant a DNA HLA typing is required. Finally note that the Wu et al. reference merely establishes that leukemic cells express WT-1 and GATA-1, thus, the elected species is inherent to the method taught by the reference.

The reference clearly anticipates the claimed invention.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
November 3, 2002